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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,857	01/23/2002	B. Nash Williams		3074

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,857	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Information Disclosure Statement

No IDS has been filed.

Specification

The abstract of the disclosure is objected to because the first "sentence" is not complete. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 2-11 and 13-16 are objected to because of the following informalities. All dependent claims should begin with the term --The--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first and sixth paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

Claims 1-11 are directed to an apparatus comprising a variety of "means for" performing certain functions. The instant specification does not provide a description of any structure for performing the recited functions. For example, claim 1 recites a "means for analyzing the DNA sequences of a biological sample", and "means for identifying specific genes within the DNA sequence". The specification, on page 4, describes the inventive device as one which analyzes body fluids, e.g. blood or saliva, and specifically discloses a tubular member ands pin-prick device for obtaining a biological sample. The specification then states on page 5 that the sample is "analyzed in the conventional manner" to determine the person's unique DNA sequence. As is well known in the art, as evidenced by extensive media coverage, there is no single "conventional method" for determining a person's genome. Further, analysis of an individual's genome would require resources and time which do not appear to compatible with a "self-contained" apparatus. As set forth by GUTTMAN et al. (TAC (1999) vol. 18 (11), pp. 694-702), at least one method of genotyping and genetic profiling requires at least a gel electrophoresis device and a scanning laser. GUTTMAN teaches that at least part of his method may be automated, but also teaches that data analysis (by a human operator) is still necessary (abstract). GOA et al. (Int'l Genome Sequencing an Analysis Conference (2000) vol. 12, pp. 60-61) teaches a method of genotyping using microchips and specific software for analysis. As late as September of 2003, LUO et al. (Genomics (9/2003) vol. 82 (3), pp. 378-389) taught that DNA must be isolated from a sample, labeled, and subjected to restriction digestion in order to build a map of a genome. WALLIN et al. (J. Forensic Sciences (2002) vol. 47 (1), pp.

52-65) teaches use of multiplex PCR and fluorescence detection in methods to differentiate and distinguish human genetic profiles. The totality of teaching in the art confirms that while it is possible to automate at least parts of methods for analyzing DNA sequences, there is no commonly accepted "conventional method" for analyzing and identifying specific genes within a DNA sequence. Further, the art discloses that the method steps and apparatus used depend on what sort of information one wishes to obtain from the sequence information. The specification does not set forth ANY description of ANY apparatus, nor any particular method steps for analyzing a DNA sample or genome. In order to correlate a specific gene with a specific physical condition, one must (a) be able to isolate and identify a single gene, (b) have access to a database which annotates or correlates phenotype (disease or physical condition) with genotype, (c) know which genes correlate to which physical conditions (i.e. the gene must have been previously identified AND must have been positively correlated with a known disease or condition). Further, in order to "identify" a gene for a correlation to be made, one must have access to a program or algorithm for sequence comparison. No apparatus or program for comparison, or database comprising correlations of known genes to known disorders is disclosed by the instant specification. It is acknowledged that databases comprising annotated sequence information are commercially available; however, these are not generally of a size practical for use in a self-contained or "stand-alone" apparatus (e.g. the NCBI database would require huge amounts of memory in a stand-alone computer). Further, 37 CFR 1.75(d)(1) provides, in part, that "the terms and phrases used in the claims must find **clear support** or

antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable **by reference to the description.**" Emphasis added by the examiner. See also 35 U.S.C. 112, sixth paragraph ("An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." (emphasis added)); see also B. Braun Medical, 124 F.3d at 1424, 43 USPQ2d at 1900 (holding that "pursuant to this provision [35 U.S.C. 112, sixth paragraph], structure disclosed in the specification is corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the quid pro quo for the convenience of employing 112, paragraph 6."); Wolfensperger, 302 F.2d at 955, 133 USPQ at 542. As the instant specification fails to describe any apparatus for performing the intended functions, or method steps, the claims are not described." See also MPEP 2181.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC

1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are not enabled because neither the specification or the prior art teach how to perform the method, or use the apparatus, with the steps/means recited in the claims. The specification provides no guidance with regard to apparatus/steps for analyzing a DNA sequence, identifying a specific gene, or correlating a gene with a specific physical condition, as set forth above. The prior art does provide guidance for analyzing specific DNA sequences, wherein the steps and materials used are subject to the type of information desired, as set forth above. It is clear from the teachings of the prior art that a DNA sample must first be isolated from a biological sample before any sequence analysis can be preformed. The claims do not recite any steps or means for isolating DNA, nor does the specification disclose any such steps or means. Next, some sort of sequence, hybridization, or fragment analysis must be performed to identify the DNA isolated. The claims recite "analysis" but do not recite any specific steps or means of sequencing, hybridizing, chromatographic separation, PCR, etc. to identify the DNA, nor does the specification teach any actual "analysis "steps. As set forth above, in order to correlate a specific gene with a specific physical condition, several requirements must be met. First, the gene must have been previously identified AND previously associated with a physical condition. It is noted that for many diseases/conditions, the mere presence of the gene does not indicate anything with regard to the physical condition. Rather, it is the presence of a mutation, SNP, or specific allele which indicates a disease or condition, or propensity toward a disease or

condition. Second, the gene must be present in an annotated database, the database must be available for searching, and one must be able to determine if the sequence in question is present in the database. Neither the claims nor specification disclose know genes, correlation to known conditions, a database which comprises such information, how to access such information or a database comprising the information, nor how to compare an identified sequence with an annotated database. While programs to compare sequences are known in the art (e.g. BLAST) and annotated databases are known in the art (e.g. NCBI), steps and apparatus for actually associating an identified (but possibly unknown) sequence with phenotypic information are not commonly known in the art, and are not claimed or disclosed anywhere.

The claims are broad as they recite an apparatus and method for analyzing any genetic material apparently using any means or method steps ever conceived of in order to correlate any gene with any physical condition. The specification does not set forth any working examples. The single Figure is a drawing of a computer workstation and does not show any specific attributes for performing the functions/steps set forth in the claims. The level of skill in the art is acknowledged to be high. However, due to the lack of guidance in the specification, and the high level of variability/uncertainty in the art for how to analyze DNA and correlate sequences with physical conditions as set forth above, it would require undue experimentation for one skilled in the art to use the claimed apparatus or perform the claims method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As set forth in MPAP 2181, "35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc)." and

"The proper test for meeting the definiteness requirement is that the corresponding structure (or material or acts) of a means (or step)-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function. See Atmel Corp. v. Information Storage Devices, Inc., 198 F.3d 1374, 1381, 53 USPQ2d 1225, 1230 (Fed. Cir. 1999). ...The disclosure of the structure (or material or acts) may be implicit or inherent in the specification if it would have been clear to those skilled in the art what structure (or material or acts) corresponds to the means (or step)-plus-

function claim limitation. See id. at 1380, 53 USPQ2d at 1229; In re Dossel, 115 F.3d 942, 946-47, 42 USPQ2d 1881, 1885 (Fed. Cir. 1997). If there is no disclosure of structure, material or acts for performing the recited function, the claim fails to satisfy the requirements of 35 U.S.C. 112, second paragraph. Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106, 1115-18, 63 USPQ2d 1725, 1731-34 (Fed. Cir. 2002)."

As the specification fails to set forth any structure, material or acts for performing the functions of claims 1-11, the claims are indefinite. Further, as one skilled in the art would not know the metes and bounds intended for a step of "analyzing" a sample genome and/or "correlating" genes with physical conditions, claims 12-16 are indefinite.

Conclusion

Claims 1-16 are rejected and objected to. The abstract is also objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
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3/19/04

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